**1. PURPOSE**

1.1. This SOP establishes the process to pre-review a request for approval (approval of new research, continuing review of research, or modification to previously approved research) or a determination whether an activity is exempt Human Research or is not Human Research or is Human Research that does not engage the Institution.

1.2. This procedure begins when the IRB receives a submission for a review for approval or a determination, including requests from other institutions when a TAMU IRB is the IRB of record for Collaborative or Multi-Site study.

1.3. This procedure ends when the submission has been placed on the agenda for an IRB meeting or handled by Non-Committee Review.

**2. REVISIONS FROM PREVIOUS VERSION**

1.1. Revised from previous version dated 5/30/17

**3. SOP Statement**

3.1. As part of IRB review, all submissions are pre-reviewed by IRB/HRPP Staff before being placed on the agenda for an IRB meeting or handled by Non-Committee Review.

3.2. The addition of a participating site to a previously approved protocol for which a TAMU IRB will serve as the IRB of record for that participating site is considered a modification to the previously approved research.

3.3. Single subject protocol exceptions are reviewed as modifications to previously approved research. [1]

4. **RESPONSIBILITY**

4.1. IRB/HRPP staff carry out these procedures

**5. PROCEDURE**

5.1. Use HRP-308 - WORKSHEET - Pre-Review to screen submission materials:

5.1.1. Identify submissions with missing materials or incomplete information

5.1.1.1. Determine if investigators have completed required institutional education and made any necessary conflict of interest disclosures.

5.1.2. Identify and document the special determinations that the IRB needs to make in order to approve research. (For example. waiver of consent, children, prisoners)

5.1.3. Identify, make, and document regulatory determinations that the institution needs to make in order to approve research (For example, NSR, IND/IDE requirements)

5.1.4. Identify any relevant local, state, or international requirements

5.1.5. Arrange for consultation to resolve local, state, or international requirements.

5.1.6. Identify other special review issues.

5.2. If the submission is a request to use an external IRB follow HRP-804 - SOP - External IRB Post-Review.

5.3. If the submission is a response to modifications required in order to secure approval of the research:

5.3.1. Evaluate whether the investigator made the required modifications.

5.3.2. If the investigator made the required modifications and no others, follow SOP: Post-Review (HRP-052)" to issue an approval. Otherwise, process as a modification.

5.3.3. If the investigator did not make the required modifications or made unrequested modifications, request clarification. Offer the investigator the opportunity to correct the submission.

5.3.3.1. If the investigator will correct the submission, have the investigator make changes and resubmit. Stop processing the current submission until changes are received.

5.3.3.2. If the investigator will not correct the submission, have the investigator

[1] Per OHRP correspondence dated 07/22/2011, protocol exceptions are considered changes to previously approved research and eligible for review via expedited procedure.

resubmit and continue processing and document the investigators response.

5.4. For all other submissions (Initial application, continuing review/closure, or modification) complete the Pre-Review Activity or review the previously completed Pre-Review Activity and revise as needed. Consider the items on HRP-308 WORKSHEET - Preview. Document all regulatory and any other contingencies in the Pre-Review workspace in the electronic system or use HRP-401 – Checklist - Pre-Review.

5.4.1. The Chair or designee ensures that issues raised by Pre-Review are covered at meetings.

5.5. If the information is not complete, contact the investigator and request clarifications or provide stipulations through the electronic system. Offer the investigator the opportunity to provide additional information.

5.5.1. Continue processing once the investigator responds to the request for additional information

5.6. For a Continuing Review Submission:

5.6.1. If the submission meets the Closure Criteria process administratively. Use Worksheet: Study Closure (HRP-335) or electronic equivalent.

5.6.2. If the Continuing Review Submission does not meet the criteria for closure then continue processing as a Continuing Review.

5.7. If the submission is a new information report determine whether the submission includes information that might represent an Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval or Termination of IRB Approval and process under HRP-024 - SOP - New Information.

5.8. Evaluate the most likely level of review and route accordingly. Use HRP-310 - WORKSHEET - Human Research Determination, HRP-311 - WORKSHEET - Engagement Determination, HRP-312 - WORKSHEET - Exemption Determination, and/or HRP-313 - WORKSHEET - Expedited Review as references.

5.8.1. If the submission does not meet the definition of Human Research because definitive plans for human subjects involvement cannot be described in the grant application and there are plans for human research during a future period of time process administratively as 'Delayed Onset'.

5.9. If the submission can be processed as a Non-Committee Review follow HRP-031 - SOP - Non-Committee Review Preparation

5.10. If the submission cannot be processed as a Non-Committee Review, place the submission on the agenda for a convened IRB meeting with the appropriate scope and follow SOP IRB HRP-040 - SOP - IRB Meeting Preparation

## 6. MATERIALS

6.1. HRP-024 - SOP - New Information
6.2. HRP-031 - SOP - Non-Committee Review Preparation
6.3. HRP-040 - SOP - IRB Meeting Preparation
6.4. HRP-052 - SOP - Post-Review
6.5. HRP-308 - WORKSHEET - Pre-Review
6.6. HRP-310 - WORKSHEET - Human Research Determination
6.7. HRP-311 - WORKSHEET - Engagement Determination
6.8. HRP-312 - WORKSHEET - Exemption Determination
6.9. HRP-313 - WORKSHEET - Expedited Review
6.10. HRP-335 - WORKSHEET - Study Closure
6.11. HRP-401 - Checklist: Pre-Review
6.12. HRP-804 - SOP - External IRB Post-Review

## 7. REFERENCES

7.1. AAHRPP elements I.1.A, I-2, I.6.B, I.7.A, I-9, II.2.A-D, II.2.E-II.2.E.2, II.2.F-II.2.F.3